

TFW

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Vladimir BAKHUTASHVILI
U.S. Serial No.: 10/795,819 Examiner: Ruth A. Davis
Filed : March 8, 2004 Art Unit: 1651
For : AMNIOTIC APOPTOSIS MODULATING SUBSTANCES

Law Offices of Albert Wai-Kit Chan, LLC
World Plaza, Suite 604
141-07 20th Avenue
Whitestone, New York 11357

October 7, 2005

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-145

Sir/Madam:

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

In accordance with his duty of disclosure under 37 C.F.R. §1.56, Applicant would like to direct the Examiner's attention to the following references which are listed below and on Form PTO/SB/08B (**Exhibit A**, 3 pages), with the individual references further attached as **Exhibits 1-21**.

1. Nahar, et al., "Infliximab Treatment of Rheumatoid Arthritis and Chrohn's Disease", The Annals of Pharmacotherapy, Vol. 37, pgs 1256-1265 (2003) [**Exhibit 1**]
2. Watanabe, et al., "Concanavalin A Induces Perforin-Mediated But Not Fas-Mediated Hepatic Injury", Hepatology, Vol. 24, No. 3, pgs 702-710 (1996) [**Exhibit 2**]
3. Xiang, et al., "Prevention by rolipram of concanavalian A-induced T-cell-dependent hepatitis in mice", European Journal of Pharmacology, Vol. 367, pgs 399-404 (1999) [**Exhibit 3**]

Applicant : Vladimir BAKHUTASHVILI
U.S. Serial No. : 10/795,819
Filed : March 8, 2004
Page : 2

4. Dzotsenidze, et al., "The Antitoxic Effect of Plaferon LB on Pesticides in Tissue Culture Model", Annals of Biomedical Research and Education, Vol. 3, pgs 180-182 (2003) [Exhibit 4]
5. Maisuradze, et al., "Some Aspects of Protective Effect of Plaferon LB During Bronchial Asthma", Annals of Biomedical Research and Education, Vol. 3, pgs 189-191 (2003) [Exhibit 5]
6. Kvezereli, et al., "Effects of Plaferon LB (PLB) on concanavalian A- induced hepatitis in mice", Annals of Biomedical Research and Education, Vol. 2, pgs 133-138 (2002) [Exhibit 6]
7. Bakradze, et al., "The Perioperative Immunocorrection by Plaferon for Colorectal Cancer Patients", Annals of Biomedical Research and Education, Vol. 2, pgs 38-41 (2002) [Exhibit 7]
8. Chichua, et al., "Biochemical Changes in Retinal Tissue During Vitreoretinal Pathology", Annals of Biomedical Research and Education, Vol. 2, pgs 189-195 (2002) [Exhibit 8]
9. Bach, Jean-Francois, "Immunotherapy of type 1 diabetes: lessons for other autoimmune diseases", Arthritis Res, Vol. 4, pgs S3-S15 (2002) [Exhibit 9]
10. Nicoletti, et al., "The Effects of a Nonimmunogenic Form of Murine Soluble Interferon-gamma Receptor on the Development of Autoimmune Diabetes in the NOD Mouse", Endocrinology, Vol. 137, No. 12, pgs 5567-5575 (2005) [Exhibit 10]

Applicant : Vladimir BAKHUTASHVILI
U.S. Serial No. : 10/795,819
Filed : March 8, 2004
Page : 3

11. Nicoletti, et al., "Early Prophylaxis with Recombinant Human Interleukin-11 Prevents Spontaneous Diabetes in NOD Mice", Diabetes, Vol. 48, pgs 2333-2339 (1999)
[Exhibit 11]
12. Lobzhanidze, et al., "Positive Effect of Plaferon-LB on Treatment of Hodgkin's Disease-Result of Immunocorrection or Apoptosis", Annals of Biomedical Research and Education, Vol. 1, pgs 170-173 (2001) [Exhibit 12]
13. Sharma, et al., "Usefulness of Gamma Intracoronary Radiation for Totally Occluded In-Stent Restenotic Coronary Narrowing", The American Journal of Cardiology, Vol. 91, pgs 595-597 (2003) [Exhibit 13]
14. Jessup, et al., "Heart Failure", The New England Journal of Medicine, Vol. 348, pgs 2007-2018 (2003) [Exhibit 14]
15. Nicoletti, et al., "Prevention and Treatment of Lethal Murine Endotoxemia by the Novel Immunomodulatory Agent MFP-14", Antimicrobial Agents and Chemotherapy, Vol. 45, No. 5, pgs 1591-1594 (2001) [Exhibit 15]
16. Genovese, et al., "Improved Survival and Antagonistic Effect of Sodium Fusidate on Tumor Necrosis Factor Alpha in a Neonatal Mouse Model of Endotoxin Shock", Antimicrobial Agents and Chemotherapy, Vol. 40, No. 7, pgs 1733-1735 (1996) [Exhibit 16]
17. Nicoletti, et al., "Endotoxin-Induced Lethality in Neonatal Mice is Counteracted by Interleukin-10 (IL-10) and Exacerbated by Anti-IL-10", Clinical and Diagnostic Laboratory Immunology, Vol. 4, No. 5, pgs 607-610 (1997)
[Exhibit 17]

Applicant : Vladimir BAKHUTASHVILI
U.S. Serial No. : 10/795,819
Filed : March 8, 2004
Page : 4

18. Nicoletti, et al., "Protection from concanavalin A (Con A)-induced T cell dependent hepatic lesions and modulation of cytokine release in mice by sodium fusidate", Clin Exp Immunol, Vol. 110, pgs 479-484 (1997) [Exhibit 18]

19. Mizuhara, et al., "T Cell Activation-associated Hepatic Injury: Mediation by Tumor Necrosis Factors and Protection by Interleukin 6", J. Exp. Med, Vol. 179, pgs 1529-1537 (1994) [Exhibit 19]

20. Tiegs, et al., "A T Cell-dependent Experimental Liver Injury in Mice Inducible by Concanavalin A", J. Clin. Invest., Vol. 90, pgs 196-203 (1992) [Exhibit 20]

21. Nicoletti, et al., "Murine Concanavalin A-Induced Hepatitis is Prevented by Interleukin 12 (IL-12) Antibody and Exacerbated by Exogenous IL-12 Through an Interferon-gamma-Dependent Mechanism", Hepatology, Vol. 32, No. 4, pgs 728-733 (2000) [Exhibit 21]

Applicant : Vladimir BAKHUTASHVILI
U.S. Serial No. : 10/795,819
Filed : March 8, 2004
Page : 5

If a telephone interview would be of assistance in advancing prosecution of the subject application, Applicant's undersigned attorney invites the Examiner to telephone him at the number provided below.

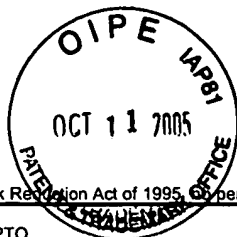
No fee is deemed necessary in connection with the filing of this Supplemental Information Disclosure Statement. However, if any additional fee is required, authorization is hereby given to charge the amount of any such fee to Deposit Account No. 50-1891.

Respectfully submitted,

Albert Wai Kit Chan

Albert Wai-Kit Chan
Registration No. 36,479
Attorney for Applicant(s)
Law Offices of
Albert Wai-Kit Chan, LLC
World Plaza, Suite 604
141-07 20th Avenue
Whitestone, NY 11357
Tel: (718) 799-1000
Fax: (718) 357-8615
E-mail: chank@kitchanlaw.com

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450 Alexandria, VA 22313-1450 or facsimile, Fax No.: 571-273-8300, transmitted to the U.S. Patent and Trademark Office on the date shown below	
<i>Albert Wai Kit Chan</i>	<i>10/7/05</i>
Albert Wai-Kit Chan	Date
Reg. No. 36,479	



PTO/SB/08B (04-03)

Approved for use through 04/30/2003. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449/PTO

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Complete if Known

Application Number	10/795,819
Filing Date	March 8, 2004
First Named Inventor	BAKHUTASHVILI, Vladimir
Art Unit	1651
Examiner Name	Ruth A. Davis
Attorney Docket Number	627-B-US

Sheet 1 of 3

NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	1	Nahar, et al., "Infliximab Treatment of Rheumatoid Arthritis and Chrohn's Disease", The Annals of Pharmacotherapy, Vol. 37, pgs 1256-1265 (2003)	
	2	Watanabe, et al., "Concanavalin A Induces Perforin-Mediated But Not Fas-Mediated Hepatic Injury", Hepatology, Vol. 24, No. 3, pgs 702-710 (1996)	
	3	Xiang, et al., "Prevention by rolipram of concanavalin A-induced T-cell-dependent hepatitis in mice", European Journal of Pharmacology, Vol. 367, pgs 399-404 (1999)	
	4	Dzotsenidze, et al., "The Antitoxic Effect of Plaferon LB on Pesticides in Tissue Culture Model", Annals of Biomedical Research and Education, Vol. 3, pgs 180-182 (2003)	
	5	Maisuradze, et al., "Some Aspects of Protective Effect of Plaferon LB During Bronchial Asthma", Annals of Biomedical Research and Education, Vol. 3, pgs 189-191 (2003)	
	6	Kvezereli, et al., "Effects of Plaferon LB (PLB) on concanavalin A- induced hepatitis in mice", Annals of Biomedical Research and Education, Vol. 2, pgs 133-138 (2002)	
	7	Bakradze, et al., "The Perioperative Immunocorrection by Plaferon for Colorectal Cancer Patients", Annals of Biomedical Research and Education, Vol. 2, pgs 38-41 (2002)	
	8	Chichua, et al., "Biochemical Changes in Retinal Tissue During Vitreoretinal Pathology", Annals of Biomedical Research and Education, Vol. 4, pgs 189-195 (2002)	
	9	Bach, Jean-Francois, "Immunotherapy of type 1 diabetes: lessons for other autoimmune diseases", Arthritis Res, Vol. 4, pgs S3-S15 (2002)	
	10	Nicoletti, et al., "The Effects of a Nonimmunogenic Form of Murine Soluble Interferon-gamma Receptor on the Development of Autoimmune Diabetes in the NOD Mouse", Endocrinology, Vol. 137, No. 12, pgs 5567-5575 (2005)	

Examiner Signature	Date Considered
--------------------	-----------------

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 120 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, Washington, DC 20231.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)		Complete if Known	
		Application Number	10/795,819
		Filing Date	March 8, 2004
		First Named Inventor	BAKHUTASHVILI, Vladimir
		Art Unit	1651
		Examiner Name	Ruth A. Davis
Sheet 2	of 3	Attorney Docket Number	627-B-US

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	11	Nicoletti, et al., "Early Prophylaxis with Recombinant Human Interleukin-11 Prevents Spontaneous Diabetes in NOD Mice", Diabetes, Vol. 48, pgs 2333-2339 (1999)	
	12	Lobzhanidze, et al., "Positive Effect of Plaferon-LB on Treatment of Hodgkin's Disease - Result of Immunocorrection or Apoptosis", Annals of Biomedical Research and Education, Vol. 1, pgs 170-173 (2001)	
	13	Sharma, et al., "Usefulness of Gamma Intracoronary Radiation for Totally Occluded In-Stent Restenotic Coronary Narrowing", The American Journal of Cardiology, Vol. 91, pgs 595-597 (2003)	
	14	Jessup, et al., "Heart Failure", The New England Journal of Medicine, Vol. 348, pgs 2007-2018 (2003)	
	15	Nicoletti, et al., "Prevention and Treatment of Lethal Murine Endotoxemia by the Novel Immunomodulatory Agent MFP-14", Antimicrobial Agents and Chemotherapy, Vol. 45, No. 5, pgs 1591-1594 (2001)	
	16	Genovese, et al., "Improved Survival and Antagonistic Effect of Sodium Fusidate on Tumor Necrosis Factor Alpha in a Neonatal Mouse Model of Endotoxin Shock", Antimicrobial Agents and Chemotherapy, Vol. 40, No. 7, pgs 1733-1735 (1996)	
	17	Nicoletti, et al., "Endotoxin-Induced Lethality in Neonatal Mice is Counteracted by Interleukin-10 (IL-10) and Exacerbated by Anti-IL-10", Clinical and Diagnostic Laboratory Immunology, Vol. 4, No. 5, pgs 607-610 (1997)	
	18	Nicoletti, et al., "Protection from concanavalin A (Con A) - induced T cell dependent hepatic lesions and modulation of cytokine release in mice by sodium fusidate", Clin Exp Immunol, Vol. 110, pgs 479-484 (1997)	
	19	Mizuhara, et al., "T Cell Activation-associated Hepatic Injury: Mediation by Tumor Necrosis Factors and Protection by Interleukin 6", J. Exp. Med, Vol. 179, pgs 1529-1537 (1994)	
	20	Tiegs, et al., "A T Cell-dependent Experimental Liver Injury in Mice Inducible by Concanavalin A", J. Clin. Invest., Vol. 90, pgs 196-203 (1992)	

Examiner Signature	Date Considered
--------------------	-----------------

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 120 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, Washington, DC 20231.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449/PTO

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Complete if Known

Application Number	10/795,819
Filing Date	March 8, 2004
First Named Inventor	BAKHUTASHVILI, Vladimir
Art Unit	1651
Examiner Name	Ruth A. Davis
Attorney Docket Number	627-B-US

Sheet 3 of 3

NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	21	Nicoletti, et al., "Murine Concanavalin A-Induced Hepatitis is Prevented by Interleukin 12 (IL-12) Antibody and Exacerbated by Exogenous IL-12 Through an Interferon -gamma-Dependent Mechanism", Hepatology, Vol. 32, No. 4, pgs 728-733 (2000)	

Examiner Signature		Date Considered	
---------------------------	--	------------------------	--

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 120 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, Washington, DC 20231.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.